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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations / Survey and Certification Group

Ref: S&C-07-34

DATE: **August 24, 2007**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Survey Guidance for a New Home Hemodialysis Water Treatment Device, the "NxStage PureFlow™ SL Water Purification System (PureFlow™)"

Memorandum Summary

- NxStage has developed a new water treatment device (i.e., PureFlow™) that is used in conjunction with the NxStage portable home dialysis machine. The device is uniquely configured and currently lacks adequate water and dialysate sampling ports.
- The Food and Drug Administration (FDA) approved PureFlow™ as a Class II device. The FDA states that the Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring safe use of the device in a facility; FDA just regulates the manufacturer.
- The NxStage portable home dialysis machine and the PureFlow™ water treatment system had been moving slowly into the dialysis market. Recently, though, this equipment is being rapidly marketed throughout the country and presents problems with the normal water monitoring requirements.
- In order to meet CMS' water/dialysate requirements for quality, one needs testing ports for sampling for water/dialysate.
- We are providing minimum standards that must be followed regarding the PureFlow™ device.

Issue

A new hemodialysis-related device, the NxStage PureFlow™ SL Water Purification System (PureFlow™), was recently introduced to the market for use in home hemodialysis. This device is used in conjunction with a portable home-dialysis machine, the NxStage System One, to treat water and make dialysate for home hemodialysis treatments. Because of the unique configuration of this device and the water and dialysate sampling ports, we are providing guidance regarding dialysis facility certification and survey expectations when this device is in use.

CMS requires testing of water used by home hemodialysis patients as specified at Section 1881(b)(9)(C) of the Social Security Act (the Act) and 42 CFR Section 405.2163(e)(5) of the Conditions for Coverage for End Stage Renal Disease (ESRD) suppliers. The PureFlow™ device has been cleared for market by the FDA as a Class II device. This FDA clearance reviews characteristics of new or modified devices and compares them to medical devices with a similar intended use. PureFlow™ device testing data, which was submitted for FDA approval, was "in vitro" (tested in a controlled environment) rather than "in actual use." While the FDA regulates manufacturers of devices for market labeling, CMS is responsible for ensuring that health care providers utilize devices in a manner that protects patient health and safety through compliance with Federal regulations. Therefore, we are issuing this Survey and Certification Memorandum to provide guidance to State agencies in the ESRD Medicare certification process.

Background

Since 1987, CMS has applied water testing standards developed by the American Association of Medical Instrumentation (AAMI). The water standards are updated by AAMI approximately every five years, and CMS adopts revised AAMI standards via formal rulemaking. The current CMS-adopted AAMI water standards are published in the AAMI document entitled "Hemodialysis Systems," second edition, 1992. The current water regulations are the following:

- **Water Bacteriology: Water Used to Prepare Dialysate.** This standard requires that bacterial levels in water should be evaluated at least monthly and after any suspected pyrogenic reactions or any modifications made to the water treatment/distribution systems or disinfection protocols. The level of microbial contamination in dialysate water should not exceed 200 colony-forming units (CFU/ml) for bacteria and have no more than five endotoxin units (EU/ml). The 1992 AAMI standards give the user a choice of doing either a test for bacterial counts or a test for endotoxin or both. AAMI states that the water samples should be taken to determine the worst possible level of contamination.

- **Water Bacteriology: Bacteriology of the Dialysate.** This standard requires that bacterial levels in dialysate should be tested at least monthly. The level of microbial contamination in dialysate should not exceed 2000/CFU/ml.

- **Maximum Level of Chemical Contaminants: Hemodialysis Water Quality.** This standard requires that the water that is used to prepare dialysate is monitored at least annually to ensure that AAMI-defined maximum allowable chemical contaminant levels are not exceeded.

- **Maximum Level of Chemical Contaminants: Chlorine/Chloramines.** The chemical-contaminant standard requires that the water used to prepare dialysate should be checked for the presence of chlorine or chloramines at least once daily. The maximum allowable chemical contaminant level is 0.5 for chlorine (free) and 0.1 for chloramines.

Application to the PureFlow™ Device

The CMS/AAMI standards are not system specific. The standards for water testing apply to all hemodialysis systems. In the future, as field data becomes available for new technologies and AAMI updates its standards, CMS may re-evaluate the water testing requirements. The PureFlow™ device is configured in a way that currently prevents access to a water sample for required CMS testing. Although the manufacturer states that "water testing is not required for these patients because the system has been validated by NxStage and cleared by the FDA for use with water that meets the Safe Drinking Water Act (SDWA) minimum quality standard," providers remain responsible for ensuring that they meet regulated health and safety requirements, and CMS remains responsible for holding providers to these standards.

CMS recognizes both the need for more information about "in use" water monitoring with the PureFlow™ device and the need to clarify how the PureFlow™ system, which does not have the necessary sampling ports to obtain appropriate water samples, can be monitored and surveyed following CMS regulations. After consultation with the FDA and the Centers for Disease Control and Prevention (CDC), the following are minimum standards that must be followed regarding the PureFlow™ device:

- **Chemical Quality of the Source and Treated Water:** The chemical quality of the treated water used for dialysis, i.e., the product water, should be analyzed initially and at least once a year at the end of the "Pak" life, or when any modifications are made to the water treatment equipment, to ensure that AAMI-defined maximum allowable chemical contaminant levels are not exceeded. The source water should meet the minimum standards of the Safe Drinking Water Act (SDWA) or have an AAMI analysis to determine that the "Pak" water treatment components will remove the contaminates. The following URL contains information on the maximum contaminant levels of the SDWA: http://www.epa.gov/safewater/contaminants/index.html#mcls.

- **Microbiological Quality of the Dialysate:** The microbiological quality of the water and dialysate should be analyzed monthly at the end of the "Sak" life using cultures and endotoxin measurements. To obtain meaningful results, a system should be established to ensure proper collection of the samples and their timely submission to the testing laboratory.

- **Chlorine/Chloramines Testing:** An appropriate volume of water should be checked for the presence of chlorine/chloramines after the preparation of each batch of dialysate. If the test shows results above AAMI's maximum allowable chemical contaminant level, then the user must discard that batch, change the "Pak," prepare another batch of dialysate and test again.

- **Training for Water/Dialysate Sampling:** The certified dialysis center must have a training and support program which is the responsibility of a registered nurse with at least 18 months experience as an RN; with experience in dialysis for at least 6 of those months and experience in teaching patients with ESRD for at least 3 of those months. As a part of the training program, patients/helpers and staff should be instructed in water/dialysate sample collection that they will be expected to perform in their homes.

- **Equipment maintenance:** Machine maintenance should include the following:
  - Exchange/disposal of the "Pak" as indicated by alarms;
  - Maintenance of components as directed by the manufacturer;
  - An agreement with the manufacturer including a list detailing the work which is done to refurbish the equipment used in exchange. Documentation of work on a specific piece of equipment must be available upon request.

As we learn more, we may supplement this information in the future. If you have further questions about this Memorandum, please contact Judith Kari, Technical Director of the ESRD Program in Survey and Certification, at judith.kari@cms.hhs.gov.

Effective Date: The information contained in this memorandum provides application of existing guidance to a new type of water treatment device and should be disseminated and effective within 30 days of the date of this memorandum.

Training: This guidance should be shared with all survey and certification staff, surveyors, their managers, and the State/RO training coordinator.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management